

## **HEALTH SERVICES QUALITY ASSURANCE IMPLEMENTATION GUIDE**

### **EXERCISE FOURTEEN**

#### **SUBJECT: BIOLOGICAL INDICATOR MONITORING OF STERILIZATION EQUIPMENT**

**PURPOSE:** The purpose of this exercise is to assist units in developing effective biological indicator monitoring programs for chemical and steam sterilization equipment in the dental and/or medical clinic. These systems are commonly referred to as “Spore Monitoring” because they work by introducing live, highly resistant, non-pathogenic spores into the sterilization cycle, and monitoring whether they are killed by the sterilization process.

**BACKGROUND:** Commandant Instruction 6600.3 requires that the sterilization process be monitored with a biological indicator as part of each clinic’s comprehensive infection control program. Spore monitoring is essential to ensure that the sterilization process is effective and that the items sterilized are safe for practitioner and patient use. Autoclave tape and bag markings alone do not determine sterility; their sole purpose is to determine whether the item has been through the sterilization heat cycle. Mechanical indicators, such as gauges and recording devices, also do not guarantee that sterilization has occurred. The most effective method for monitoring the sterilization process is to place a biological indicator in a test or challenge pack at regularly prescribed intervals. This procedure monitors the effectiveness of the following components of the sterilization process:

1. Function of the Sterilizer
2. Quality and Quantity of the Sterilant
3. Type and Method of Packaging
4. Sterilizer Packing and Loading Methods

**DISCUSSION:** Spore monitoring must be conducted weekly. When a sterilizer is used less than weekly, each sterilization cycle must be test. The first step in establishing an effective spore monitoring program is to delineate responsibilities in writing and designate a clinic staff member and an alternate who will be responsible for monitoring the program. Enclosure (1) provides a sample memorandum which may be used in whole or in part for this purpose.

Enclosure (2) provides the names and estimated cost information for several commercial spore monitoring systems. Some systems, such as Proof Plus by AMSCI and Attest by 3M, will accomplish this task entirely in-house. These systems require the initial purchase of a test incubator at a cost of approximately \$200. As an alternative, clinics may use third party services which provide the biological indicators for clinic use, perform laboratory testing of the indicators, and return the results to the clinic; no in-house incubation and interpretation of results is required. Emory University is one firm which provides such a service.

Clinics must maintain a log of all tests conducted and test results. At a minimum, this log must include sterile pack identification data, sterilization date, sterile pack expiration date, and spore monitoring test results. Logbooks or forms are usually available as part of commercially available systems. Enclosure (3) provides an example of a spore monitoring log. Spore monitoring test results must be retained for three years.

**ACTION:** All Coast Guard health care facilities operating steam and/or chemical sterilization equipment will conduct an ongoing biological indicator monitoring program. A clinic staff member and an alternate will be designated in writing as responsible for this function and maintain a log documenting all testing.

Enclosures:

- (1) Sample Letter of Designation of Responsibility for Sterilization Monitoring
- (2) Examples of Commercially Available Biological Monitoring Systems with Estimated Cost

U.S. Department  
of Transportation

United States  
Coast Guard



Commandant  
United States Coast Guard

Staff Symbol:  
Phone: ( )  
Fax: ( )  
Email:

## MEMORANDUM

From: Chief, Health Services Division

Reply to  
Attn of:

To: Designee's Name  
Alternate Designee's Name

Subj: DESIGNATION OF RESPONSIBILITY FOR STERILIZATION MONITORING

1. You are hereby assigned responsibility for conducting weekly biological monitoring of all sterilization done at this clinic.
2. This responsibility includes:
  - a. Labeling all autoclaves and chemiclaves to be monitored by name, number or location;
  - b. Ensuring that weekly testing is conducted for all sterilization equipment using biological indicator test. When a sterilizer is used less than weekly, each sterilization cycle must be tested.
  - c. Ensuring that tests are promptly incubated and test results returned;
  - d. Maintaining a log documenting all biological indicator testing conducted, including dates and test results;
  - e. Notifying the Chief, Health Services Division of positive test results, and ensuring that sterilizers testing positive are taken out of service until repaired; and
  - f. Assuring that adequate supplies of test kits are procured and maintained in stock.
3. In the event of your absence, for any reason, (ALTERNATE'S NAME HERE) will act as the alternate.

SIGNATURE OF THE CHIEF, HSD

ENCLOSURE (1)

## OMMERCIALLY AVAILABLE BIOLOGICAL MONITORING SYSTEMS

NOTE: This list provides a sampling of resources. Other organizations may offer monitoring systems which will meet our requirements. Clinics interested in these systems should contact companies at telephone numbers listed below for specifics and current price information.

1. Source: American Sterilizer Company (AMSCO)  
Telephone: 800-333-8838

Test Name: Proof Plus (For Steam and Ethylene Oxide)

Estimated Cost: Incubator \$238

Tests: \$197.90 per 100 tests  
(\$1.98 per test)

2. Source: 3M Health Care Group, Medical-Surgical Division  
Telephone: 612-733-4925

Test Name: Attest

Estimated Cost: Incubator \$220

Tests: Attest #1262 (for steam)  
\$163 per 100 tests  
(\$1.63 per test)  
Attest #1264 (for Ethylene Oxide)  
\$163 per 100 tests  
(1.63 per test)

3. Source: Emory University  
Telephone: 404-727-6763

Test Name: Emory University  
Sterilization Monitoring Service  
(For Steam and Ethylene Oxide)

Estimated Cost: \$120 (12 Test Kit - \$10.00 per test)  
\$375 (48 Test Kit - \$7.81 per test)

With this system, tests are sent to a laboratory in Atlanta, GA. Negative results are returned via mail to the facility, while clinics are notified of positive results via telephone.

**ENCLOSURE (2)**